

**REMARKS**

Favorable consideration and allowance are respectfully requested for claims 17 and 38 in view of the foregoing amendments and the following remarks.

In the Office Action dated January 27, 2003, claims 1-38 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite; claims 1-11, 13, 22 and 23 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. ("5,776,492"); claims 1-8, 10-13, 19, 21, 22, 25 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. ("5,516,803"); claims 1-8, 10, 11, 13, 19, 20, 22, 24 and 26 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. ("5,958,452"); claims 1-8, 10, 19, 20, 22, 24 and 26 were rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. ("5,958,452"); claims 9 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. ("5,516,803"); claims 27-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. ("5,516,803") in view of methods as described in Remington's Pharmaceutical Sciences, 1990, pages 1641-1647; and claims 1, 2 and 6-18 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-7 and 11 of co-pending Application no. 10/016,130.

The Office Action indicated that Claims 17 and 38 would be allowable if rewritten in independent form including all of the limitations of the base claim

and any intervening claims and if the rejections under 35 U.S.C. § 112 were overcome. Applicant has amended claims 17 and 38 in independent form and claims 17 and 38 are believed to be allowable.

In the interests of facilitating a timely issuance of claims 17 and 38, which the Office Action indicated were allowable, the Applicant is immediately pursuing only those claims indicated as allowable. The Applicant has cancelled claims 1-16 and 18-37 despite Applicants' position that the cancelled claims are allowable over the cited references. Applicants' election to pursue claims 17 and 38 in the present application is not, nor should it be interpreted to be, indicia of any agreement with the positions set forth in the Office Action with respect to the cancelled claims.

Rejections under 35 U.S.C. § 112, second paragraph

Claim 17 was rejected for indefiniteness, as claim 17 depended from claim 1. Claim 1 was asserted to be confusing because it could allegedly be interpreted in multiple ways. Claim 1 was also rejected because it was unclear what the "compound" is. As currently amended, claim 17 is directed to a formulation that comprises a compound of tramadol hydrochloride and diclofenac sodium, the compound having the indicated solubility characteristics. Applicant submits that the claim clearly describes the compound and that the claim is appropriately definite.

Claim 1 was also rejected under 35 U.S.C. § 112 because it was unclear what "formed in situ" does to the formulation. An explanation of in situ

formation of certain embodiments of the compound is disclosed at least in paragraphs 11-13 of the specification. Paragraphs 17, 18, 21 also relate to the in situ formation of certain embodiments of the compound. As can be appreciated from these paragraphs, and the disclosure in general, the in situ formation of the compound affects the water solubility characteristics of the compound. In this way, the in situ-formed compound causes the oral pharmaceutical form of administration to be at least partially sustained release. Additionally, in certain embodiments, tramadol release becomes at least partially retarded (depending on the amount of acidic substance being present during the preparation of the administrative form) by the in situ formation of a compound of tramadol and another active substance, without the use of a sustained release matrix and/or a sustained release coating.

Claim 27 was rejected because the term "partially sustained release" is not art recognized. Applicant has removed the words "at least partially sustained-release" term from the preamble of pending claim 38.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, as it relates to pending claims 17 and 38, is respectfully requested.

#### Provisional Obviousness-type Double Patenting Rejection

Claims 1, 2 and 6-18 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-7 and 11 of co-pending Application no. 10/016,130. Applicant

respectfully submits that the claims of the present application are patentably distinct from the claims of co-pending Application no. 10/016,130. A basic requirement of the various embodiments of the present application is that tramadol and diclofenac and/or their respective physiologically compatible salts are formulated "together" in order to allow in situ formation of a compound of tramadol with low water solubility. In contrast thereto, a basic requirement of the embodiments of Application no. 10/016,130 is that tramadol and diclofenac and/or their respective physiologically compatible salts are present in separate subunits which are "separately" formulated. Accordingly, Applicant respectfully submit that the subject matter of the present claims is not obvious in view of the claims of the earlier application and Applicant requests withdrawal of the provisional obviousness-type double-patenting rejection.

CONCLUSION

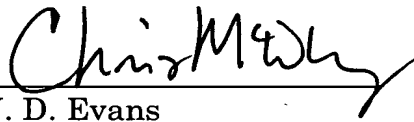
In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A petition for an Extension of Time is submitted herewith and is believed to be effective to extend the period for response to the date listed below, in view of 37 C.F.R. 1.7. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #148/50932).

Respectfully submitted,

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